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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 1

<i>Complete if Known</i>	
Application Number	09/654,227
Filing Date	August 31, 2000
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1617
Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

U.S. PATENT DOCUMENTS

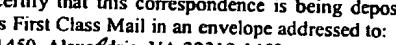
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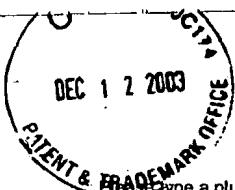
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SH	C1	Ellman Declaration with Exhibits A-M

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Name:	Sharon McDaniel
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U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
SM	A1	4,217,347		Horovitz et al.	08-12-1980
	A2	5,001,113		Williams et al.	03-19-1991
	A3	5,824,667		Spona et al.	10-20-1998
	A4	6,083,528		Elliesen et al.	07-04-2000
	A5	6,121,465		Mohr et al.	09-19-2000
SM	A6	RE37,564		Spona et al.	02-26-2002

FOREIGN PATENT DOCUMENTS					
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		Office ³	Number ⁴		
SM	B1	DE	3022337	A1	Eiger et al.
	B2	WO	95/07081	A1	Koninckx
	B3	WO	97/10827	A1	Petit et al.
SM	B4	WO	98/27929	A2	Nashed

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SM	C1	Elstein et al., "Advances in Oral Hormonal Contraception," <i>Zentralbl Gynakol</i> 117 (1995) 559-565			
	C2	Oelkers et al., "Effects of the new progestogen and antimineralocorticoid dihydrospirorenone," <i>Acta Endocrinologica</i> 1992: 126 Suppl. 4, p. 71			
	C3	Oelkers et al., (1991) "Dihydrospirorenone, a New Progestogen with Antimineralocorticoid Activity: Effects on Ovulation, Electrolyte Excretion, and the Renin-Aldosterone System in Normal Women" <i>Journal of Clinical Endocrinology and Metabolism</i> , Vol. 73, No. 4, 837-842			
	C4	Oelkers, "Effects of oral contraceptives on the renin – aldosterone system: overview and report on a new natriuretic progestogen," <i>Advances in Contraception</i> , 7 Suppl. 3 (1991) 195-206			
SM	C5	Kindl et al., "Increasing Oral Bioavailability of Progesterone by Formulation," <i>Journal of Steroid Biochemistry</i> , 1978, Vol. 9, pp. 83-84			

Examiner Signature		Date Considered	3/19/04
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821	C6	Whitehead et al., "Absorption and metabolism of oral progesterone," <i>British Medical Journal</i> , 22 March 1980, pp. 825-827
	C7	Maxson et al., "Bioavailability of oral micronized progesterone," <i>Fertility and Sterility</i> , Vol. 44, No. 5, November 1985, pp. 622-626
	C8	Chakmakjian et al., "Bioavailability of Progesterone with Different Modes of Administration," <i>The Journal of Reproductive Medicine</i> , Vol. 32, No. 6, June 1987, pp. 443-448
	C9	Hargrove et al., "Absorption of oral progesterone is influenced by vehicle and particle size," <i>Am J Obstet Gynecol</i> , Vol. 161, No. 4, October 1989, pp. 948-951
	C10	Kohno et al., "Pharmacokinetics and Bioavailability of Diltiazem (CRD-401) in Dog," <i>Arzneim.-forsch./Drug Res.</i> , 27 (II), No. 7 (1977), pp. 1424-1428
	C11	Nürnberg, "Manufacturing and Properties of Pharmaceutical Spray-Dried Products," <i>Acta Pharmaceutica Hungarica</i> 48, 19-35, 1978 (and English translation)
	C12	Lehto et al., "The Effect of pH on the In-vitro Dissolution of Three Second-generation Sulphonylurea Preparations: Mechanism of Antacid-sulphonylurea Interaction," <i>J. Pharm. Pharmacol.</i> 1996, 48: 899-901
	C13	Clarke et al., "Factors Influencing Comparative Bioavailability of Spironolactone Tablets," <i>Journal of Pharmaceutical Sciences</i> , Vol. 66, No. 10, October 1977, pp. 1429-1432
	C14	"Bioavailability and Bioequivalence," <i>Biopharmacy</i> , Chapter 7 (English translation part ½ of page 202, Chapter 7)
	C15	Berger et al., (1992) "Influence of Different Progestogens on Blood Pressure of Non-Anaesthetized Male Spontaneously Hypertensive Rats" <i>Contraception</i> 46: 83-97
	C16	Skouby, (2000) "The rationale for a wider range of progestogens" <i>Climacteric</i> , Vol. 3, (Suppl. 2); 14-20
	C17	Norman et al., (2000) "Drospirenone" <i>Drugs of the Future</i> 2000, 25(12): 1247-1256
	C18	R. Krattenmacher, (2000) "Drospirenone: pharmacology and pharmacokinetics of a unique progestogen" <i>Contraception</i> 62, 29-38
	C19	Fuhrmann et al., (1996) "The Novel Progestin Drospirenone and its Natural Counterpart Progesterone: Biochemical Profile and Antiandrogenic Potential" <i>Contraception</i> , 54: 243-251
821	C20	Parsey et al., (2000) "An Open-Label, Multicenter Study to Evaluate Yasmin, a Low-Dose Combination Oral Contraceptive Containing Drospirenone, a New Progestogen" <i>Contraception</i> , 61: 105-111

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First Named Inventor	Wolfgang HENK et al.
Group Art Unit	1617
Examiner Name	M. Bahar

Attorney Docket Number

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SH	C21	Krause et al., "Isolation and Identification of Spirorenone Metabolites from the Monkey (Macaca Fascicularis)," <i>Steroids</i> , Vol. 40, No. 1, July 1982, pp. 81-90	
	C22	Krause et al., "Determination of Plasma Levels of Spirorenone, a New Aldosterone Antagonist, and One of its Metabolites by High-Performance Liquid Chromatography," <i>Journal of Chromatography</i> , 230 (1982) 37-45	
	C23	"Spirorenone," <i>Drugs of the Future</i> , Vol. 10, No. 6, 1985, pp. 479-481	
	C24	Wilson et al., (1984) "A prospective controlled study of the effect on blood pressure of contraceptive preparations containing different types and dosages of progestogen" <i>Brit. J. Obstet Gynecol</i> 91, 1254-1260	
	C25	Nichols et al., (1993) "Effect of four combined oral contraceptives on blood pressure in the pill-free interval" <i>Contraception</i> 47, 367-376 (1993)	
	C26	Oelkers et al., (1974) "Effects of Progesterone and Four Synthetic Progestagens on Sodium balance and the Renin-Aldosterone System in Man" <i>J. Clin. Endocrinol Metab</i> 39, 882-890	
	C27	Rylance et al., "Natural progesterone and antihypertensive action," <i>British Medical Journal</i> , Vol. 290, Jan. 5, 1985, p. 13-14	
	C28	Luotola, "Blood Pressure and Hemodynamics in Postmenopausal Women During Estradiol-17 β Substitution," <i>Annals of Clinical Research</i> , Vol. 15, Suppl. 38 1983	
	C29	Mashchak, et al., "Estrogen Replacement Therapy and Hypertension," <i>The Journal of Reproductive Medicine</i> , Vol. 30, No. 10 (Supp)/October 1985, p. 805-810	
	C30	Rajkumar et al., "Hormonal Therapy Increases Arterial Compliance in Postmenopausal Women," <i>JACC</i> , Vol. 30, No. 2, August 1997:350-6	
	C31	Hayward et al., "Effect of hormone replacement therapy on non-invasive cardiovascular haemodynamics," <i>Journal of Hypertension</i> , 1997, Vol. 15, No. 9, p. 987-993	
	C32	Mercuro et al., "Estradiol-17 β Reduces Blood Pressure and Restores the Normal Amplitude of the Circadian Blood Pressure Rhythm in Postmenopausal Hypertension," <i>American Journal of Hypertension</i> , Vol. 11, No. 8, Part 1, pp. 909-913	
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	C34	Wren et al., "The effect of type and dose of oestrogen on the blood pressure of post-menopausal women," <i>Maturitas</i> , 5 (1983) 135-142	
SH	C35	Oelkers, "Reply to Letter to the Editor," <i>Gynecol Endocrinol</i> , 2000, 14:476-478	

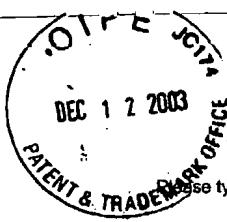
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				Examiner Name	M. Bahar
				Attorney Docket Number	PLOVIN-1A

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	C37	Mercuro et al., "Effects of Acute Administration of Transdermal Estrogen on Postmenopausal Women with Systemic Hypertension," <i>The American Journal of Cardiology</i> , Vol. 80, September 1, 1997, 652-655
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